

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/927,791	SHARAF ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ling-Siu Choi	1713	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 06/27/2005.
2. ☒ The allowed claim(s) is/are 8,9 and 19-21.
3. ☒ The drawings filed on 10 August 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All   b) ☐ Some\*   c) ☐ None   of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br/>Paper No./Mail Date _____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</li> <li>6. <input type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date _____</li> <li>7. <input type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____</li> </ol> |
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### DETAILED ACTION

1. This Office Action is in response to the Amendment filed June 27, 2005. Claims 1-7 and 10-18 were canceled and claims 8-9 and 19-21 are now pending.

#### *Allowable Subject Matter*

2. Claims 8-9 and 19-21 are allowable over the closest references: Smith et al. (US 5,747,249) and Ansorge et al. (US 5,912,118).

<b>Calibration Standard</b> for a fluorescent polynucleotide separation apparatus, comprising
<b>at least four polynucleotides of different known length</b> each polynucleotide labeled with a different fluorescent dye having a distinctive spectral profile having a peak
wherein the lengths of the polynucleotides differ from one another such that, upon electrophoretic separation, the peak of the spectral profile of any one of the dyes does not significantly overlap the peak of the spectral profile of any of the other dyes

(summary of claim 8)

Smith et al. disclose a method to separate and detect tagged polynucleotide, comprising (a) providing a plurality of polynucleotides, each being tagged with a fluorophore, (b) resolving to separate one of the plurality of tagged polynucleotides from other tagged polynucleotides differing by a single nucleotide using an electrophoretic procedure capable of resolving tagged polynucleotides differing by a single nucleotide, and (c) detecting the resolved

Art Unit: 1713

tagged polynucleotides by means of the fluorophore, wherein the tagged polynucleotides are obtained from one of a set of primer extension reactions in which each of the tagged primer oligonucleotides used in one of the sets is distinguishable by its spectral characteristics from the tagged primer oligonucleotides used in the other sets (claims 1 and 8). However, Smith et al. do not teach or fairly suggest a calibration standard comprising the use of at least four polynucleotides each having **different known length** and each being labeled with a **different fluorescent dye** having a distinctive spectral profile having a peak.

Ansorge et al. disclose a method to sequence nucleic acids, comprising (a) providing a mixture of labeled nucleic acid fragments of different length with fluorescent dyes, (b) separating the labeled nucleic acid fragments according to size by gel electrophoresis, and (c) determining the nucleic acid sequence by labeling the individual fragments (col. 2, lines 28-40; col. 6, lines 36-40; claims 6, 9, 12). However, Ansorge et al. do not teach or fairly suggest a calibration standard comprising the use of at least four polynucleotides each having **different known length** and each being labeled with a **different fluorescent dye** having a distinctive spectral profile having a peak.

In light of the above discussion, it is evident as to why the present claims are patentable over the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Art Unit: 1713

***Conclusion***

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ling-Siu Choi whose telephone number is 571-272-1098.

If attempt to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu, can be reach on 571-272-1114.



LING-SUI CHOI  
PRIMARY EXAMINER

July 5, 2005